

Appl. No. : 09/447,227
Filed : November 22, 1999

REMARKS

Claims 33, 34, 38, 41, 42, 48, 49, and 54-83 are pending in this application. Claims 34, 38, 48, and 49 have been amended. Claims 35 and 39 are canceled in the present amendment. Claims 36, 37, 40, 43-47, 50-53, and 84-87 were canceled in a previous amendment. Support for the amendments is found in the specification and claims as filed. Specifically, support for the amendments to Claims 34 and 38 is found in Fig. 1A.

Interview

Applicants thank Examiner Nasser for the courteous and helpful interview conducted with Applicants' representative, Laura Johnson, on April 26, 2007.

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 35 and 39 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Although Applicants do not necessarily agree with the propriety of the rejection, Claims 35 and 39 have been canceled without prejudice, solely to advance prosecution of the remaining claims. Applicants reserve the ability to pursue the canceled claims, or similar claims, in one or more continuing patent applications. The rejection is therefore moot.

Claim Rejection - 35 U.S.C. §103(a) – Allen *et al.* in view of Gilligan *et al.* and Picha

Claims 33-35, 38, 39, 41, 42, and 56-83 have been rejected under 35 U.S.C. §103(a) as obvious over Allen *et al.* (U.S. Pat. No. 5,322,063) in view of Gilligan *et al.* ("Evaluation of a Subcutaneous Glucose Sensor out to 3 Months in a Dog Model," Diabetes Care, Vol. 17, No. 8, August 1994, page 882) and Picha (U.S. Pat. No. 5,706,807). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143. Evidence of unobvious or unexpected advantageous properties can rebut *prima facie* obviousness. No set number of

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examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987) (Evidence showing that the claimed herbicidal compound was more effective than the closest prior art compound in controlling quackgrass and yellow nutsedge weeds in corn and soybean crops was sufficient to overcome the rejection under 35 U.S.C. 103, even though the specification indicated the claimed compound was an average performer on crops other than corn and soybean.).

Claim 34 recites a method of measuring glucose in a biological fluid comprising, *inter alia*, the step of “providing an implantable device comprising ... a housing ... wherein said housing comprises a first portion and a second portion, wherein a curvature of the second portion is greater than a curvature of the first portion” Claim 38 recites a method of monitoring glucose levels, comprising, *inter alia*, the step of “providing ... a device comprising a housing ... wherein said housing comprises a convexly curved portion over which a sensing membrane and a first domain are located”

As depicted in Figure 2, Allen *et al.* teaches a planar glucose sensor with a membrane layer overlying an electrode region on one side of the sensor – the electrode region is neither convexly curved nor has a curvature. Gilligan *et al.* teaches an implantable sensor wherein the sensing region, although curved, is recessed flush with the housing – it does not protrude. Picha is cited as teaching a device including an angiogenic layer surrounding an implantable device; however, Picha does not teach a protruding sensor portion that is convexly curved or has a curvature.

Applicants note that a protruding region that is convexly curved or has a curvature offers advantages over the configurations of the prior art, namely, superior performance in the formation of vasculature in the sensor interface region. The overall curvature of the surface on which the sensing region is located, including rounded edges, invokes a generally uniform foreign body capsule around that surface, decreasing inflammatory response and increasing analyte transport at the device-tissue interface. The curvature ensures that the sensing region is resting against the tissue and that when tissue contraction occurs, forces are generated downward on the sensing region so that the tissue attachment is maintained. The downward forces bring the tissue into contact with porous biointerface materials used for ingrowth-mediated attachment and

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for biointerface optimization. Accordingly, the curvature of the sensing region, not just its protrusion, is important to the process of vascularization.

Because Allen *et al.*, Gilligan *et al.*, and Picha do not disclose a convexly curved portion or a portion having a curvature, and because Applicants' protruding convexly curved portion (or a protruding portion having a curvature) is responsible for superior vascularization when compared to prior art configuration, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a) – Allen *et al.* in view of Gilligan *et al.* and Picha

Claims 48, 49, 54, and 55 have been rejected under 35 U.S.C. §103(a) as obvious over Allen *et al.* in view of Gilligan et al., and Picha, and further in view of Ward et al. (U.S. Pat. No. 5,711,861). To establish a *prima facie* case of obviousness, the prior art references must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143.

Claims 48 and 54 depend from Claim 34 and Claims 49 and 55 depend from Claim 38. As discussed above, Claim 34 recites a method of measuring glucose in a biological fluid comprising, *inter alia*, the step of “providing an implantable device comprising ... a housing ... wherein said housing comprises a first portion and a second portion, wherein a curvature of the second portion is greater than a curvature of the first portion” Claim 38 recites a method of monitoring glucose levels, comprising, *inter alia*, the step of “providing ... a device comprising a housing ... wherein said housing comprises a convexly curved portion over which a sensing membrane and a first domain are located”

Ward et al. is cited for teaching use of an enzymatic membrane. Ward et al. does not teach a protruding electrode region or a region that is convexly curved or has a curvature, and thus does not overcome the deficiencies of Allen *et al.*, Gilligan et al., and Picha. Applicants therefore respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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